

A decorative graphic on the left side of the slide, resembling a DNA double helix. It consists of two intertwined strands, one colored in shades of pink and the other in shades of purple. The strands are connected by horizontal rungs, also in pink and purple, creating a continuous helical pattern.

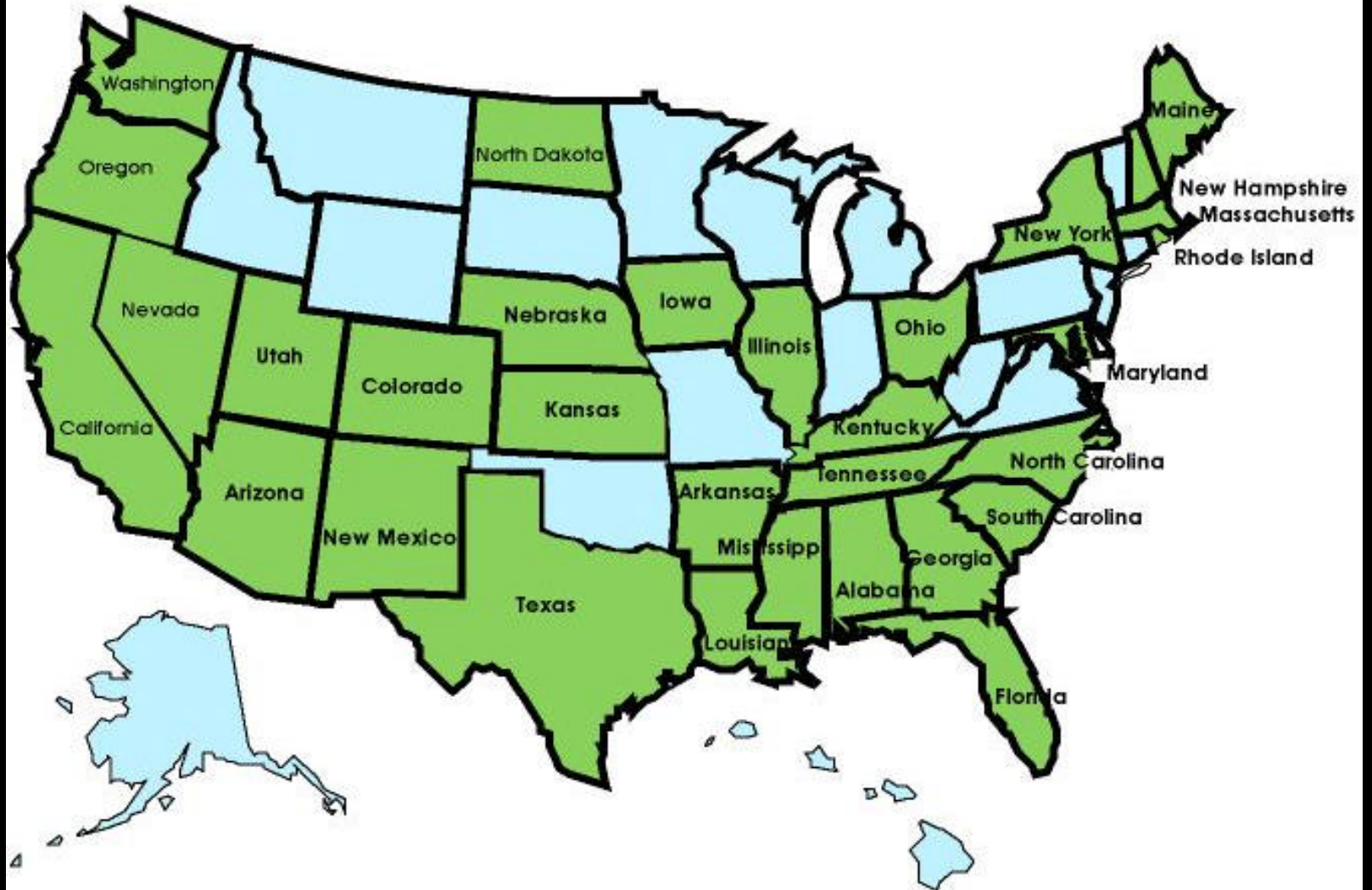
National Materials Program Working Group



What is an Agreement State?

- ⇒ State that has agreement with NRC
- ⇒ NRC relinquishes authority to regulate radioactive materials in that state
- ⇒ some exceptions
(federal facilities, power reactors)

NRC/Agreement States



Green = Agreement State
Blue = Non-Agreement State



Agreement State Expansion

1959 - AEA amended with Section 274

1962 - First Agreement State (Kentucky)

1971 - Twenty-third Agreement State (MD)
50% of licenses in Agreement States

2000 - Thirty-second Agreement State (OK)
>75% of licenses in Agreement States

2003 - Thirty-five Agreement States(?)
>80% of licenses in Agreement States



Where are we now?

- > most licenses issued by Agreement States
- > concurrent smaller NRC fee base of licensees
- > no longer “parent-child” relationship
- > increased use of Agreement State expertise
- > need to optimize resources



NMP Working Group Members

Co-Chairs

Kathy Allen (IL)

Jim Myers (NRC)

Carol Abbott (NRC)

Chip Cameron (NRC)

Cindy Cardwell (TX)

Joe Decicco (NRC)

Liz Drinnon (GA)

Tom Hill (GA)

Linda Howell (NRC)

Jake Jacobi (CO)

Bob Walker (MA)

Duncan White (NRC)

Charles Cox (NRC)

Advisor

Fred Combs (NRC)



Purpose of NMP Working Group

- > look at future of radiation regulatory programs
- > define “national materials program”



Outline of the Working Group Report




MISSION OF NATIONAL MATERIALS PROGRAM WORKING GROUP

Provide the Commission with options for maintaining infrastructure of supporting rules, guides and other necessary program elements



Direction to NMP Working Group

...6 key issues to address

- 
- > mission statement of NMP
 - > delineation of roles for NRC, Agreement States, CRCPD, OAS
 - > scope of activities covered by NMP & need for statutory changes
 - > establish formal program coordination mechanisms
 - > performance indicator & assessment procedures
 - > budgeting of resources



Additional Issues for the NMP Working Group

⇒ focus on functional rather than
organizational changes

⇒ don't limit effort to AEA material



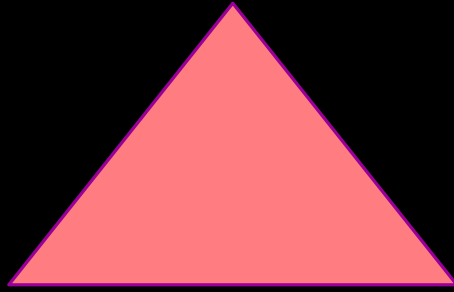
NMP Working Group Philosophy

“To create a true partnership of the NRC and the States that will ensure protection of public health, safety, and the environment while...



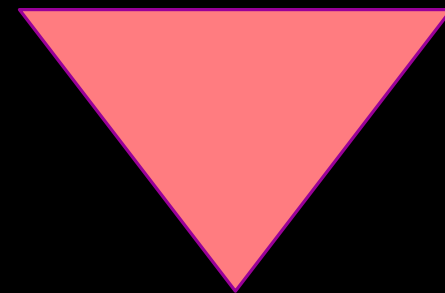
- ☆ optimizing resources of federal, state, professional and industrial org.
- ☆ accounting for individual agency needs
- ☆ promoting consensus on regulatory priorities
- ☆ promoting consistent exchange of information
- ☆ harmonizing regulatory approaches
- ☆ recognizing state and federal needs for flexibility

Development of Product

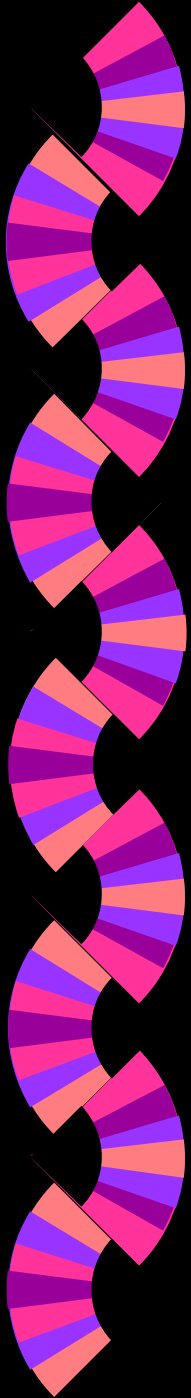


“Bottom-up”
“Functional”

rather than...



“Top-down”
“Programmatic”





i.e....

First

→ determine what a NMP
must accomplish

Second


→ determine how that can
be accomplished



Options



Part I...



Essential Elements of a Radiation Regulatory Program

- ✓ IMPEP criteria
- ✓ CRCPD criteria



Essential Program Elements

Materials Licensing Guidance

Materials Inspection Guidance

Materials Licensing & Inspection –
Alternative for States

Performing Materials Inspections

Issuing Materials Licenses

Reciprocity

Technical Guidance Documents

Training, Qualifications & Experience of
Regulatory Personnel

Regulatory Program Reviews

Regulatory Program for General Licensees

Certification Programs

Rulemaking



Options for Implementing Program Elements

- ⇒ define how currently done
- ⇒ brainstorm different options
- ⇒ evaluate options against mission statement



Evaluation Example

	1	2	3	4	5	6
1	0	0	0	0	0	0
2	+	+	+	+	+	0
3	+	+	+	+	+	0
4	-	0	-	-	-	0
5	+	+	0	+	0	0

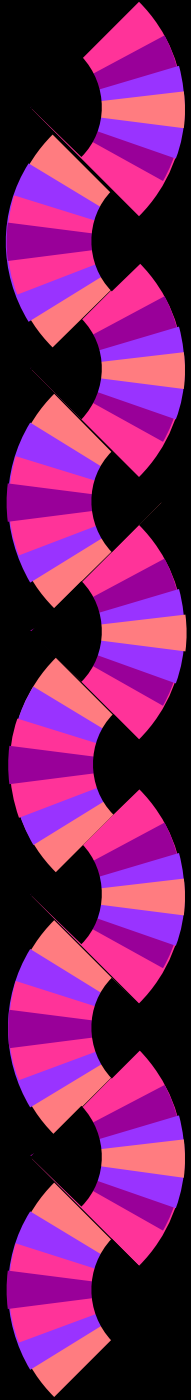
Recommendations:

- NRC/AS jointly develop an agenda and priorities for developing licensing guidance
- NRC/AS either use working groups to develop guidance or direct other organizations/entities to develop guidance when appropriate

Program Element
Recommendations



Common Attributes





Common Attributes

- ★ shared goals/decision-making
 - use consensus process
 - establish priorities
 - recognize current successes
 - recognize individual legal/jurisdictional parameters



Common Attributes

★ shared resources

- identify and use centers of expertise
- use alternate available resources
- establish communications clearinghouse
- reduce duplication of effort



Common Attributes

- ★ shared responsibility
- resource commitment



Options



Part II...



Structures to Support Attributes

- consultative
- advisory
- consensus
- autonomy



Consultative Structure

Ad hoc process of seeking input;
NRC establishes goals and priorities,
seeks input from other entities,
determines compatibility



Advisory Structure

Standing entities provide input and advice; NRC collects input and advice on establishing priorities, taking action; NRC accepts or rejects



Consensus Structure

Solidarity in group decisions
made by most concerned; priorities,
program agendas, activities,
compatibility jointly set by
NRC and states



Autonomy Structure

Each entity operates independently;
NRC and Agreement States each
do what is necessary for themselves
within their own jurisdiction according
to their own priorities,
compatibility not necessary



Consultative Structure



- easy to manage
- inexpensive
- provides for input



- easy to ignore
- no mandate to implement advice
- not a true partnership

Advisory Structure



- easy to manage
- inexpensive
- provides for input



- easy to ignore
- no mandate to implement advice
- not a true partnership

Autonomy Structure



- easy to manage
- ultimate flexibility to operate program



- resource intensive
- promotes inconsistency
- no partnership
- hampers communication

Consensus Structure



- opportunity for input from all
- spirit of true partnership
- promotes consistency
- resource saving upon implementation
- shared responsibility

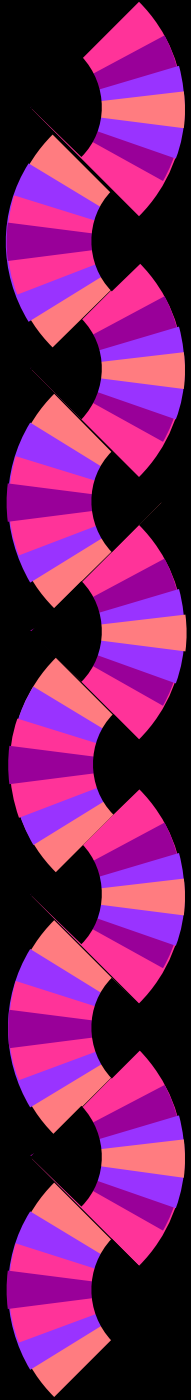


- negotiations can be time & resource intensive
- participants must be empowered
- diffused decision-making

Consensus Structure



Alliance





Options



Part III...



Alliance

Cooperative process between the States and NRC* that identifies radiation safety regulatory priorities and the mean to address those priorities

*Although the process was piloted between the States and NRC, there is no reason to believe that it should not involve other federal and state regulatory agencies on radiation issues



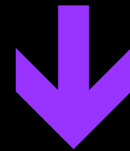


Alliance

- ★ Regulatory decision-makers
- ★ Administrative core
- ★ Other stakeholders



Alliance Membership



“decision-makers”

- state radiation regulatory program managers
- NRC materials program managers



Role of the Alliance

- jointly establish regulatory priorities, agenda
- identify centers of expertise
- recognize current successes
- identify alternate resources
- define/make assignments
- commit resources
- evaluate progress on assignments



Administrative Core Membership



"support staff"



Role of Administrative Core

- logistical planning of Alliance
agenda/meeting arrangements
- facilitation of Alliance meetings
- tracking of Alliance
assignments/products
- maintenance of communications
clearinghouse
- central contact/coordination
point for Alliance



Stakeholders

- licensees
- public
- professional organizations
- industry organizations
- other federal agencies





Rulemaking and Guidance

- ⇒ History - what works,
what has not worked
- ⇒ Work Product
- ⇒ Rules
- ⇒ Compatibility



History/Experience

- ☆ General - NRC lead
- ☆ PET Guidance
- ☆ Industrial Radiography
- ☆ Irradiators



History - NRC Lead

- NRC develops initial draft
- one state rep may participate
- state review often depends on compatibility
- Commission adopts
 - may change compatibility
- SSR's developed & adopted
- states adopt as appropriate

History - NRC Lead



- NRC resources
- States can rely on NRC



- resource intensive
- time delay
- no partnership
- Commission determines compatibility
- centers of expertise may not be consulted



History - PET Guidance

- existing technology becomes widely used
- creates “new” center of expertise
- no NRC involvement
- SSR committee review

History - PET Guidance



- SSR committee review
- some states developed expertise



- lack of information sharing
- no guidance documents
- no partnership
- no leaders
- many states revisit same issue



History - IR

- need identified
- request from licensees to hold radiographers responsible
- 1 state, 2 state, 3 state 4
- NRC follows
- states continue to be centers of expertise



History - IR



- continued state involvement
- solutions to issues
- respond to problems



- NRC slow to adopt
- not consistently implemented



History - Irradiators

- need identified - incident
- NRC established working group
 - state and federal
- regulations drafted
- Commission adopts
 - compatibility set
- SSR's developed & adopted
- states adopt

History - Irradiators



- early implementation of working group concept
- short time frame for product
- centers of expertise consulted



- Commission determines compatibility



Alliance Work Products

■ Alliance

1. define work product

- rule, guidance, procedure
- scope, depth, time frame
- define resources needed (stakeholders, “associates”)



Alliance Work Products

■ Alliance

2. work done on voluntary basis

- all must work within resources
- highest priorities come first
- NRC & states can work on lower priority



Alliance Work Products

■ Alliance

3. set schedule - based on

- alliance consensus
- WG or WG member priority (accelerate)
- available resources



Alliance Work Products

■ Alliance

4. approve or reject

- WG level decision
- no formal Alliance vote
- “Suggested” work product - Agencies adopt.
- routine Alliance priority setting



Alliance Work Products

Working Group

1. select leader(s)
2. develop product
3. report progress
4. have product peer reviewed
5. submit product to Alliance core



Alliance Work Products

- Administrative core

1. track progress
2. report progress to Alliance



Regulation Development Under the Alliance

(subset of Work Products)

- 1 Alliance meets, establishes priorities
- 2 Identify regulatory change
- 3 Define work product
- 4 Identify centers of expertise;
establish working groups
- 5 Set schedule



Regulation Development Under the Alliance

- 6 WG drafts rule, statement of consideration, regulatory analysis; suggest compatibility
- 7 Standing Compatibility Review Group assigns compatibility category
- 8 Peer review



Regulation Development Under the Alliance

- 9 WG reviews comments - if major change, back to step 6
- 10 If no major change, draft becomes a Suggested Regulation and distributed to Alliance
- 11 Each agency adopts product



Standing Review Committee

Most states believed the results of the 1998 complete compatibility review were valuable. Since then, compatibility decisions have reverted to the NRC, with disagreement between the NRC and the states. A standing compatibility committee could allow a consensus decision based on the principles of the original compatibility working group.



Standing Review Committee

ISSUE:

Can a Suggested Regulation be a matter of strict compatibility if it was not a priority for the Alliance?



Options



Part IV...



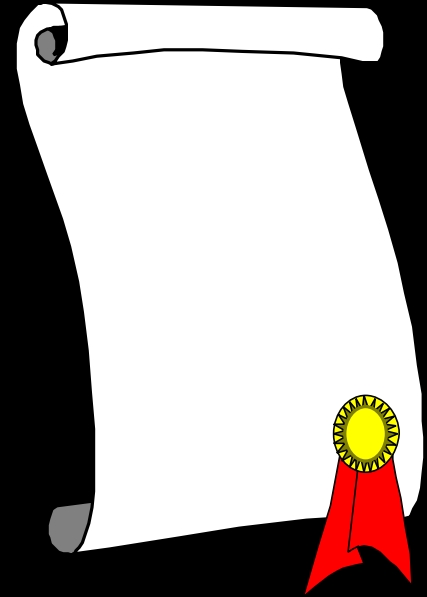
Implementation of Alliance

How do we...

- ? formalize structure
- ? ensure functionality
- ? provide direction
- ? provide accountability

Formalizing Structure

- “Handshake”
- Simple document describing roles
- MOUs between participating parties
- “Agreements”
 - Modify existing Agreements
 - Create new Agreements
- Legislative Changes





Ensure Functionality

- Are tasks being accomplished?
- Is “alliance” working properly?
- Who is the judge? NRC? OAS? CRCPD?

**Different structures = different
ways to ensure functionality**

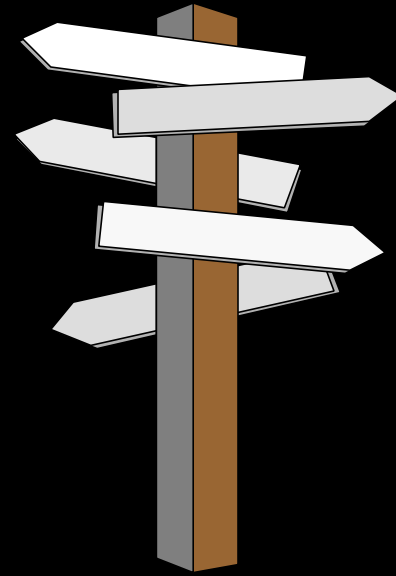



Provide

Direction

&

Accountability





Range of Implementation Options

- NRC divides out Reactors & Materials with Materials portion acting as “Agreement State” reporting with other AS to new Agency
- Re-structure Commission to include State membership
- REQUIRE all states to become AS



Other “Brainstorms...”

- Create structure similar to FDA or EPA for state assumption of authority
- NRC sets regulations -- All states implement plans under NRC rules
- NRC pays states to implement programs
- AS licensees pay NRC for oversight
- States obtain “grants” from NRC for roles in regulation or guidance development



Implementation of Alliance

- What will it cost in...

- ? 

- ? \$



The PLAN:

- **Look at current situation & identify current costs**
- **Compare options against current situation and identify if costs go up or down for NRC and States for each viable option**



The “Report” & Limitations

- ▶ Level of detail in the final report
- ▶ Recommendation for a separate working group



Stakeholder Involvement

- ❖ activities to date
- ❖ focus of outreach activities
- ❖ planned activities



Activities to Date

- established website
- developed communication plan
- held tabletop exercise at OAS annual meeting (October 2-3, 2000)
- published articles in November 2000 Health Physics Society Newsletter
- drafted questions for use with focus group discussions
- requested feedback to focus questions at NERHC and STC-HPS meetings



- stakeholder outreach sessions held:
- poster session at CRCPD annual meeting (May 15-16, 2000)
 - NRC Standards Developing Organization (July 27, 2000)
 - NRC regions and headquarters (July-November, 2000)
 - OAS meeting (October 2, 2000)
 - South Texas Chapter – Health Physics Society (November 11, 2000)
 - NERHC (November 15, 2000)



Focus of Outreach Activities

- get information out on NMP and working group activities
- generate discussion with stakeholders
- generate interest, especially with internal stakeholders
- initiate use of focus questions
- obtain public comment on draft report



Planned Activities

- hold public meeting(s) in February, 2000
- expand use of focus questions
- submit articles for NMSS and CRCPD newsletters
- make presentations to external stakeholders
- make second round of presentations to NMSS and regional staff
- link NMP website to other sites



NMP Working Group To-Do List

- ☞ obtain additional stakeholder input
- ☞ finalize Options...Part IV
- ☞ prepare report
- ☞ report to Commission
May 2001

